

(13) 日本特許庁 (JP)

(12) 公表特許公報 (A)

(11) 特許出願公表番号

特表2003-503101

(P2003-503101A)

(43) 公表日 平成15年1月28日 (2003.1.28)

(51) Int. Cl. ⁷	識別記号	FI	ナコード (参考)
A61F 2/06		A61F 2/06	4C060
A61B 17/00	320	A61B 17/00	320 4C097
A61M 25/02		A61M 25/02	4C167

審査請求 未請求 予備審査請求 有 (全 18 頁)

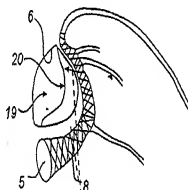
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(36) (22) 出願日	平成12年6月28日 (2000.6.28)		スイス国スッチェン、バーレンルディシュ
(55) 優先文書出日	平成13年12月17日 (2001.12.17)		トラーセ 14
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(87) 国際公開日	平成13年1月4日 (2001.1.4)		ン 9
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(54) 【発明の名称】 僧帽弁不全の治療装置と方法

(57) 【要約】

僧帽弁輪拡張の拡張装置は、2つの状態を有する伸長体 (8) を含む。第1の状態において伸長体 (8) は冠状洞 (5) に挿入可能で、冠状洞 (5) の形状に適合できる形状を有する。伸長体 (8) は、冠状洞 (5) 内に配置された時に、第2の状態へ移行して小さな曲率半径となることができ、これにより冠状洞 (5) の曲率半径および僧帽弁輪 (6) の曲率半径と周長が縮小される。



【特許請求の範囲】

【請求項1】 冠状洞 (5) に挿入可能な寸法を有するとともに2つの状態を有する伸長体 (8 ; 8' ; 8'') を含む、第1の状態において前記伸長体 (8 ; 8' ; 8'') は冠状洞 (5) の形状に適合できる形状を有し、また前記伸長体 (8 ; 8' ; 8'') は前記第1の状態から第2の状態に移行して小さな曲率半径となることができ、もって前記伸長体 (8 ; 8' ; 8'') が冠状洞 (5) 内に配置された時に冠状洞 (5) の曲率半径が縮小し、僧帽弁輪 (6) の周囲長が縮小するようになっている僧帽弁輪拡張治療装置。

【請求項2】 前記伸長体 (8 ; 8'') を大きな曲率半径から小さな曲率半径となるように曲げおよび短縮して第2の状態へ移行させるための手段 (9 ; 2 ; 26, 27) を更に含む請求項1に記載された僧帽弁輪拡張治療装置。

【請求項3】 短縮によって前記伸長体 (8) を曲げおよび短縮する手段を前記移行手段 (9 ; 2 ; 26, 27) が含む請求項2に記載された僧帽弁輪拡張治療装置。

【請求項4】 第2の状態へ移行させる記憶材料を前記伸長体 (8 ; 8'') が含む請求項1に記載された僧帽弁輪拡張治療装置。

【請求項5】 前記伸長体 (8) がステントを含む請求項1または請求項2に記載された僧帽弁輪拡張治療装置。

【請求項6】 前記伸長体 (8'') が幾つかのステント部分 (23~25) を含む、前記曲げ手段 (9 ; 2 ; 26, 27) が前記ステント部分の間隔距離を短縮させるワイヤー (26, 27) を含む請求項2に記載された僧帽弁輪拡張治療装置。

【請求項7】 僧帽弁の後葉状器官 (2) の近くで冠状洞 (5) 内に伸長体 (8 ; 8' ; 8'') を挿入する段階、および冠状洞 (5) の曲率を小さくして僧帽弁輪 (6) の周囲長を縮小させるように、冠状洞 (5) 内に配置された前記伸長体 (8 ; 8' ; 8'') を曲げおよび短縮させる段階を含む僧帽弁輪の周囲長縮小方法。

【請求項8】 前記伸長体 (8 ; 8'') を曲げおよび短縮する前記段階が前記伸長体の短縮によって行われる請求項7に記載された僧帽弁輪の周囲長縮小方

法。

【請求項9】 記憶材料を前記伸長体(8')に用いて第2の状態に移行させる請求項7または請求項8に記載された僧帽弁輪の周周長縮小方法。

【請求項10】 前記伸長体(8'')が幾つかのステント部分(23~25)で形成され、前記伸長体(8'')を曲げるために前記ステント部分(23~25)の間隔距離を短縮させるのにワイヤー(26, 27)を用いる請求項7または請求項8に記載された僧帽弁輪の周周長縮小方法。

【発明の詳細な説明】

【0001】

本発明は、僧帽弁不全を処置、特に僧帽弁輪の拡張を処置する装置および方法に関するものである。

【0002】

僧帽弁不全は虚血性疾患、僧帽装置の変性疾患、リウマチ熱、心内膜炎、先天性心臓疾患、心臓胸筋疾患(cardiomyopathy)のような幾つかの原因で生じる。僧帽弁の4つの主な構造要素は輪、2つの葉状器官、索、および乳頭筋である。さまざまな組合せにおいてそれらのいずれか1つまたは全ては損傷したり、不全を生じ得る。輪拡張は、その原因に係わらずに僧帽弁不全の病理の主要因である。さらに、多くの患者は後輪の拡張を主因または唯一の原因とする僧帽弁不全を有する。何故なら、前葉状器官の輪は心臓基底の繊維性骨組織に固定されているために拡張しないからである。

【0003】

僧帽弁不全の自然経過の研究で、重大な僧帽弁不全を患っている全ての無症候性患者は通常は5年以内に厳しい障害に進むことを見出した。現在、その処置は僧帽弁の交換または修復から成り、そのいずれの方法も心臓を切開しての外科術を必要とする。交換は機械弁または生体弁のいずれを使用しても実施できる。

【0004】

器械弁は血栓症の危険性をもたらし、抗凝固処置を必要としてあらゆる潜在的な危険を伴うのに対し、生体組織は耐用性が限られるという影響を受ける。交換による他の危険は、心内膜炎の危険性である。これらの危険性、およびその他の弁に関連する合併症は、弁を修復することによって著しく減少される。

【0005】

僧帽弁の修復は、基本的に正常な前葉状器官が存在しているならば、理論的に可能である。修復の基本的な4つの技術は、輪形成外科リングの使用、疾患のある後葉状器官の四角形部分の切除、細長い索の短縮、および後葉状器官索の前葉状器官への移動を含む。

【0006】

輪形成外科リングは、耐用性のある輪拡張復を達成するために必要である。
一般的なリングの全ては左心房の僧帽弁輪に隣接した僧帽弁の後葉状器官に沿って縫合される。デュラン・リングは弁を完全に囲むものに対して、他のものは前葉状器官に向かって開放されている。このリングは、本来のカーペンティア・リングのように剛性が大きくてもよく、また、デュラン・リングまたはコスグロープ・エドワード・リングのように可撓性なるも非弾性であってよい。

【0007】

僧帽弁不全の効果的な処置は、現在のところ心肺バイパス、大動脈交差クランプ、および心臓麻痺阻止 (cardioplegic arrest) の全てを使用して心臓を切開する外科術を必要とする。

【0008】

或る群の患者には、これは特に危険である。高齢の患者、左心室機能の低下した患者、腎臓疾病の患者、大動脈が厳しく石灰化した患者、既に心臓外科術を受けた患者、または他の合併症のある患者は特に、たとえ修復が完全でなくとも、組織を貫くことのない手法が最も好適のようである。現在の趨勢は、心肺バイパスをせずに、組織をさほど冒さない冠動脈外科術に向かっており、同様にPTCAもしばしば付随する僧帽弁不全の修復のために組織をさほど冒さない方法を要求する。

【0009】

それ故に、本発明の第1の目的は、心肺バイパスや胸部および心臓の切開を必要とせずに、僧帽弁不全を処置する装置および方法を提供することである。

【0010】

本発明の第2の目的は、組織をさほど冒さない外科術を用いて僧帽弁輪を縮小させることである。

【0011】

前記目的、およびその他の目的は、請求項1で定義される装置、および請求項7で定義される方法によって達成される。

【0012】

本発明によれば、僧帽弁不全の治療装置は、冠状洞内に挿入可能な寸法を有す

るとともに2つの状態を有する伸長体を含み、第1の状態において伸長体は冠状洞の形状に適合できる形状を有し、また伸長体は前記第1の状態から第2の状態に移行して小さな曲率半径となることができ、これによって伸長体が冠状洞内に配置された時に冠状洞の曲率半径および僧帽弁輪の周囲長が縮小される。

【0013】

伸長体を大きな曲率半径から小さな曲率半径となるように曲げおよび短縮して第2の状態へ移行させるための手段が提供される。

【0014】

この移行手段は、好ましくは非対称の短縮によって伸長体を曲げおよび/または短縮する手段を含むことができる。

【0015】

さらに、伸長体は、第2の状態へ移行させる記憶材料を含むことができる。

【0016】

好ましい例では、伸長体はステント (stent) を含んで構成される。代替例において、本発明装置は幾つかのステント部分を含み、前記曲げおよび/または短縮手段はステント部分の間隔距離を短縮するワイヤーを含むことができる。

【0017】

第2の見地によれば、僧帽弁輪の円周を縮小する方法は、僧帽弁の後葉状器官の近くで冠状洞に伸長体を挿入する段階、およびその後冠状洞の曲率を小さくして僧帽弁輪の円周を縮小させるように、冠状洞内に位置された本体を曲げおよび/または短縮する段階を含む。

【0018】

したがって、本発明は僧帽弁輪に接近した冠状洞の位置を利用する。これは、現在のカテーテルガイド技法を使用して修復を可能にする。

【0019】

冠状静脈は心筋から右心房へ血液を排出する。小さい静脈は心房内へ直接血液を排出し、より大きい静脈は大動脈と関連して、実質的に僧帽弁開口および輪を取り囲む冠状洞内へ延在する。これは、心房隔壁とオイスクイ後洞との間の右心房内へ排出するまえに、左心房壁と心室心臓層との間の脂肪層内に位置す

る後房室系の溝内に延在する。

【0020】

成人では、冠状洞の筋道は僧帽弁の後葉状器官の内側付着箇所の5～15mm以内に近づく。正常体重の成人の解剖において実施した予備測定は、内側付着箇所で5.3±0.6mmの距離、後葉状器官の横方向において約10mmという同様な結果を示している。冠状洞の円周は、心門で18.3±2.9mm(5.8±0.9mmの後葉状器官直径を与える)であり、また後葉状器官の横方向に沿って9.7±0.6mm(3.1±0.2mmの直径に等しい)であった。

【0021】

本発明は、添付図面を参照した以下の好適例の説明からさらによく理解されるであろう。

【0022】

図1は、脂肪組織で満たれた後房室系溝1の心臓部分を通る横断面図である。同図は、僧帽弁の後葉状器官2、および房心筋および室心筋の隣接部分3、4を示す。冠状洞5は、僧帽弁輪6に隣接し、後葉状器官2の付着箇所7の後方に示されている。冠状洞5は実質的に僧帽弁輪6を取り囲むので、曲がった冠状洞5の曲率半径の縮小も僧帽弁輪6の直径および円周の縮小をもたらす。

【0023】

図2の装置は、例えばニショナル(Nitonal)のような記憶金属、または他の同様な本来形状の記憶を有する材料で形成されて一時的に図2に示された他の形状となるように強制されることのできる、図3に示された伸長体8を含む。この伸長体8は、以下に説明するように互いに取り付けられ、また移動を可能にすることのできる1つ、2つまたはそれ以上の記憶金属製の螺旋またはその他の形状のばね9を含む。伸長体8に沿って幾つかのフック10が半径方向外方へ突出するように取り付けられている。これらのフック10は図2のカバー・シート11で覆われている。

【0024】

伸長体8は、図4に示される安定具12によって伸長さなわち延長状態となるように強制される。この安定具12は、2本のアーム13をロッド15の先端1

4に有し、また1つの固定手段16をロッド15の基礎に有する。ロッド15の両端の間隔距離は、冠状洞5内に挿入されたときの伸長体8の望ましい長さ一至する。

【0025】

アーム13は図4に示す位置と、図6に示すようなロッド15と整合する位置との間を自由に移動できる。固定手段16は2つの固定ノブ17を有しており、これらの固定ノブ17は2つのばねブレード18でロッド15から半径方向外方へ向けて押圧されている。したがって、伸長体8は安定具12のロッド15上で押された後、アーム13と固定ノブ17の間で伸長されて、図5に示されるように最終的にその伸長状態にてアーム13と固定ノブ17との間に固定される。

【0026】

ロッド15は先端14と固定手段16との間で比較的堅いが、冠状洞5の形状に追従するように曲がることはできる。固定手段16の近くの安定具11の金属ワイヤーは、静脈の曲がり具合に容易に追従できるようにもつと曲がり易い。

【0027】

前記伸長体8は以下の方法で冠状洞5内に配置される。

【0028】

合成材料製の導入用シート(図示せず)が静脈系へのアクセスを得るために使用できる。静脈系へのアクセスを得たならば、導入用シートを通し、静脈系を経て金属製の長い案内ワイヤー(図示せず)が冠状洞5へ進められる。この案内ワイヤーはX線マーカーを備えており、冠状洞5内での案内ワイヤーの位置が監視できる。

【0029】

伸長体8は、図5に示されるように安定具12上に固定され、合成材料製の長いカバー・シート11内に導入される。その後、この集合体は導入シートおよび静脈系を通して冠状洞5へ向けて押されて案内ワイヤーに乗る。僧帽弁19が中央開閉20を有して示されている図8に示すように、冠状洞5内で伸長体8を正確に位置決めした後、カバー・シート11は引き戻されて冠状洞5内で伸長体8を露出させる。この操作は、伸長体8上のフック10を冠状洞5の壁および心

属に突き立てできるようにする。伸長体8は安定具12上に依然として固定されているので、フック10は冠状溝5の壁と伸長体8を伸長すなわち延長させた状態で係合する。

【0030】

図6に示されるように、ばねブレード18をロッド15へ向けて押圧することにより伸長体8を固定手段16から解放させるためにカテテル21が案内ワイヤーおよびロッド15の上を押し進められる。この動きは固定ノブ17並びにアーム13を伸長体8との係合から解放し、伸長体8は図9に示されるように短縮し、また僧帽弁輪6へ向けて曲がる結果としてその後部分を前方(図9に矢印で示すように)へ移動させる。この移動は僧帽弁輪6の円周を縮小させ、これにより中央開閉20を閉じる。

【0031】

図7は、伸長体8の円周部に沿うワイヤー9およびフック10の構造の一部を示し、これによりフック10の少なくとも幾つかの相互連結部分が元の形状となるように短縮されたときに、伸長体8は非対称に短縮して曲がりを生じる。

【0032】

図10、図11は伸長体8'の代替例を示しており、これは冠状溝5内に挿入されたときに僧帽弁輪6に最も隣接した冠状溝5の壁に係合する開放U形リング形状の中実ワイヤーである。伸長体8'は記憶金属材料で構成され、元の形状に復帰した時には図11に示されるような曲がりを生じる。開放リング8'の元の形状への復帰は、当業者に明らかなような幾つかの方法で開始されることができ

【0033】

図12および図13に示される第3の実施例の伸長体8''は、3つのセント部分23~25を含み、それらの部分は伸長体8''の一端、その中央、および伸長体8''の他端にそれぞれ位置される。これらのセント部分23~25は位置が固定されるように従来手段によって図示されるように冠状溝5内に位置することができる。それらはワイヤー26、27で連結され、それらのワイヤーは静脈系の外側から操作されて隣接するセント部分23、24そして24、25の間

間距離が縮小される。さらに詳しくは、それらの距離は非対称的に縮小される、すなわち、冠状溝5の側で大きく、僧帽弁輪6の後部分に隣接して最も大きく縮小される。これにより伸長体8''は、図13に示すように曲がり、冠状溝5を僧帽弁輪6に対して押圧して開閉20を閉じる。

【0034】

本発明は、僧帽弁輪の拡張を縮小させるために設計された、冠状溝内に配置される装置を提供するものである。この装置は、後葉状器官の付着箇所から、現在の輪形成外輪が配置される距離を大きく超えない或る距離に配置され、冠状溝はそのような装置を保持するために十分に長い行程に亘る。装置はカテテル技術または他のいずれかの適当な技術によって位置決めされ、現在の切開外移方法にかかわる安全性を与える。装置は冠状溝における血栓症を防止するように設計されるか、ヘパリン被覆を施され、したがってアスピリン、チクロペディンまたは抗凝固治療の必要性を減少させる。

【0035】

本発明の精神および範囲から逸脱することなく前記装置および方法の改良が当業者によってなされ得ることを理解すべきである。

【図面の簡単な説明】

【図1】

心臓の一部の横断面図。

【図2】

本発明装置の第1例の模式図。

【図3】

本発明装置の第1例の模式図。

【図4】

図2、図3に示す装置を冠状溝内に配置する時に使用可能な器具を、図5、図6と共に示す模式図。

【図5】

図2、図3に示す装置を冠状溝内に配置する時に使用可能な器具を、図4、図6と共に示す模式図。

【図6】

図2、図3に示す装置を冠状洞内に配置する時に使用可能な器具を、図4、図5と共に示す模式図。

【図7】

図2に示す第1例の部分拡大図。

【図8】

図2、図3に示す装置を冠状洞内に配置した状態を図9と共に示す模式図。

【図9】

図2、図3に示す装置を冠状洞内に配置した状態を図8と共に示す模式図。

【図10】

本発明による第2例装置を冠状洞内に配置した状態を図11と共に示す模式図

【図11】

本発明による第2例装置を冠状洞内に配置した状態を図10と共に示す模式図

【図12】

本発明による第3例装置を冠状洞内に配置した状態を図13と共に示す模式図

【図13】

本発明による第3例装置を冠状洞内に配置した状態を図12と共に示す模式図

【図1】

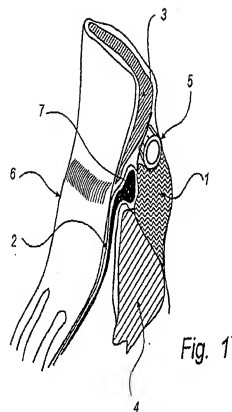


Fig. 1

【図2】

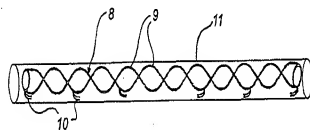


Fig. 2

【図3】

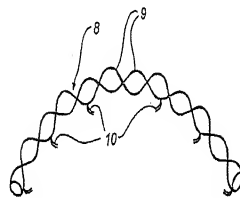


Fig. 3

【図4】

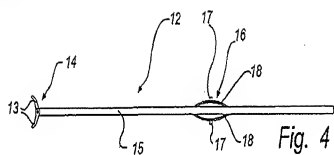


Fig. 4

【図5】

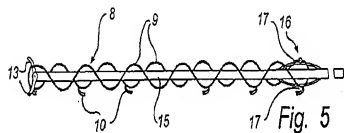


Fig. 5

【図6】

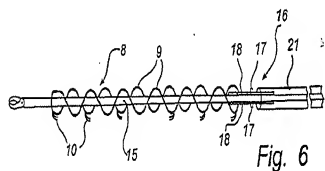


Fig. 6

【図7】

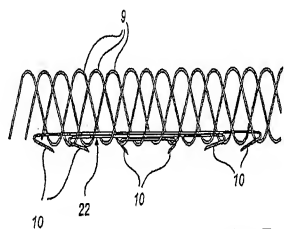


Fig. 7

【図8】

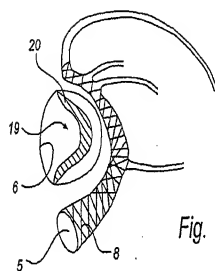


Fig. 8

【図9】

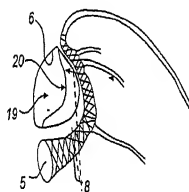


Fig. 9

【図10】

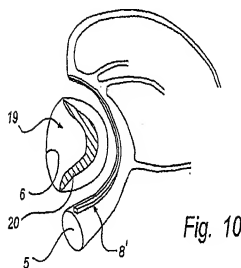


Fig. 10

【図11】

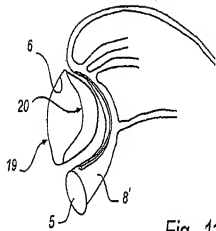


Fig. 11

【図12】

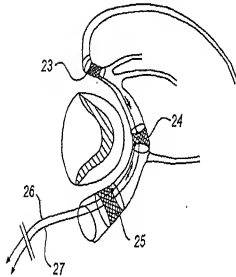


Fig. 12

【図13】

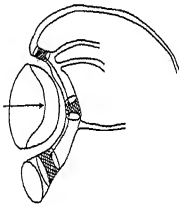


Fig. 13

【国際調査報告】

1

INTERNATIONAL SEARCH REPORT

International application No. PCT/SE 00/01369			
A. CLASSIFICATION OF SUBJECT MATTER IPC: AGIF 2/06 According to International Patent Classification (IPC) as to both technical classification and IPC			
B. FIELD SEARCHED Information dissemination searched (classification system followed by classification system) IPC: AGIF Documentation searched, other than abstracts: documentation to the extent that such documents are included in the fields searched SE, JP, FI, NO classes as above (Documentation data has been searched during the international search (none of data has not, where practicable, search error and))			
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.		
A	DE 19656042 A1 (FISCHLA, HANS-REINER), 15 January 1998 (15.01.98), abstract + figure --- 1-10		
A	EP 0727239 A2 (DAIG CORPORATION), 21 August 1996 (21.08.96), abstract --- 1-10		
A	US 5163955 A (CHARLES S. LOVE ET AL), 17 November 1992 (17.11.92), abstract --- 1-10		
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> One patent family member.			
<table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> * Special categories of cited documents "X" documents relating to the prior art of the invention as it is not considered to be of particular relevance "Y" other documents are published as to other international filing date in which the invention was first disclosed in any form (written or oral) in which it is not considered to be of particular relevance "Z" documents relating to the prior art of the invention as it is not considered to be of particular relevance "W" documents relating to the prior art of the invention as it is not considered to be of particular relevance "U" documents relating to the prior art of the invention as it is not considered to be of particular relevance "V" documents relating to the prior art of the invention as it is not considered to be of particular relevance "T" documents relating to the prior art of the invention as it is not considered to be of particular 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Date of the actual completion of the international search 8 Sept. 2000 Name and mailing address of the ISA/ Swedish Patent Office Box 5025, S-102 42 STOCKHOLM Fax: +46 8 666 02 16			
Date of mailing of the international search report 23-10-2000 Authorized officer Hélène Eriksson/EIS Telephone No. +46 8 792 32 00			

Form PCT/ISA/190 (second sheet) (July 1999)

INTERNATIONAL SEARCH REPORT

Information on patent family members

08/05/90 PCT/SE 00/01369

International application No.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19605042 A1	15/01/98	NONE	
EP 0727239 A2	21/08/96	CA 2150784 A	15/08/96
		CA 2153178 A	15/08/96
		EP 0727238 A	21/08/96
		JP 8286658 A	15/10/96
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		EP 0569458 A	18/11/93
		JP 7504091 T	11/05/95
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		US 5356376 A	05/07/94
		US 5356371 A	05/07/94
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Form PCT/ISA/210 (patent family search) (July 1993)

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(英)指定国 EP(AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, I T, LU, MC, NL, PT, SE), OA(BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG), AP(GH, GM, K E, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), EA(AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, C A, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, K E, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, R U, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW

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